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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Food and Drug Administration/Xavier University PharmaLink Conference: Increasing Product Confidence

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) Cincinnati District, in co-sponsorship with Xavier University, is announcing a public conference entitled "FDA/Xavier University PharmaLink Conference: Increasing Product Confidence". The PharmaLink conference seeks solutions to important and complicated issues by aligning with the strategic priorities of FDA, featuring presentations from key FDA officials, global regulators, and industry experts. Each presentation challenges the status quo and conventional wisdom, to create synergies focused on finding solutions which make a difference. The experience level of the audience has fostered engaged dialogue, which has led to innovative initiatives.

DATES: The public conference will be held on March 16, 2016, from 8:30am to 5 p.m.; March 17, 2016, from 8:30 a.m. to 5p.m.; and March 18, 2016, from 8:30 a.m. to 12:20 p.m.

ADDRESSES: The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207; 513-745-3016.

FOR FURTHER INFORMATION CONTACT: For information regarding this document: Steven Eastham, Food and Drug Administration, Cincinnati South Office, 36 East 7th St., Cincinnati, OH 45202; 513-246-4134, steven.eastham@fda.hhs.gov.

For information regarding the conference and registration: Mason Rick, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207-5471; 513-745-3016, rickm@xavier.edu.

SUPPLEMENTARY INFORMATION:

I. Background

The most pressing challenges of the global pharmaceutical industry require solutions, which are inspired by collaboration, to ensure the ongoing health and safety of patients. These challenges include designing products with the patient in mind, building quality into the product from the onset, selecting the right suppliers, and considering total product lifecycle systems. Meeting these challenges requires vigilance, innovation, supply chain strategy, relationship management, proactive change management, and a commitment to doing the job right the first time. FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices.

II. Meeting Information

A. Registration

There is a registration fee. The conference registration fees cover the cost of the presentations, training materials, receptions, breakfasts and lunches for the 2.5 days of the conference. There will be onsite registration. The cost of registration is as follows:

Table 1.--Registration Fees[1]

Attendee Type	Standard Rate
Industry	$1,895
Small Business (<100 employees)	$1,295
Supplier	$600
Start-up Manufacturer	$300
Academic	$300

Media	Free
Government	Free

[1]The fourth registration from the same company is free; all four attendees must register at the same time.

The following forms of payment will be accepted: American Express, Visa, Mastercard, and company checks. To register online for the public conference, please visit the "Registration" link on the conference Website at http://www.XavierPharmaLink.com. FDA has verified the Website address, but is not responsible for subsequent changes to the Website after this document publishes in the Federal Register.

To register by mail, please send your name, title, firm name, address, telephone number, email address, and payment information to: Xavier University, Attention: Mason Rick, 3800 Victory Pkwy., Cincinnati, OH 45207-5471. An email will be sent confirming your registration.

Attendees are responsible for their own accommodations. The conference headquarters hotel is the Downtown Cincinnati Hilton Netherlands Plaza, 35 West 5th St., Cincinnati, OH 45202, 513-421-9100. To make reservations online, please visit the "Venue & Logistics" link at http://www.XavierPharmaLink.com. The hotel is expected to sell out during this timeframe, so early reservation in the conference room-block is encouraged.

If you need special accommodations due to a disability, please contact Mason Rick (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance of the conference.

B. Purpose and Scope of Meeting

The public conference helps fulfill the Department of Health and Human Services and FDA's important mission to protect the public health. The conference will engage those involved in FDA-regulated global supply chain quality and management through the following topics:

- Office of Compliance Update
- Data Integrity

- Medicines and Healthcare products Regulatory Agency (MHRA) Update: Strategic Priorities and Initiatives
- Operating in India and Southeast Asia
- Serialization
- Integrity of Supply
- Office of Pharmaceutical Quality Update
- How to Measure Quality Culture
- Pharmaceutical Metrics and the Value Proposition
- Office of Regulatory Affairs Update
- The 21st Century Cures Act: Goals and Impact
- International Conference on Harmonisation Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management
- Barriers to Quality and Supply Chain Excellence
- Proactive and Systematic Quality Implementation: Case Studies across functional areas
- FDA and MHRA Investigator Insights

The conference includes:

- Networking by topic
- Case Studies
- Small Group Discussions
- Action Plans
- Keynote dinner at Paul Brown Stadium (Home of the Cincinnati Bengals)

The conference helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The conference also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121) by providing outreach activities by Government Agencies to small businesses.

Dated: January 21, 2016.

Leslie Kux,

Associate Commissioner for Policy

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